



**El-Andalous Audit on liquid, Sterile drops, Lyophilizer and Penicillin
area
CAPA Action Plan**

Form No.: QPF31000/02

Effective Date: 13/03/2016

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Corrective Action Plan
For El-Andalous audit on liquid, Sterile drops, Lyophilizer and Penicillin area
Audit Report Dated 30/10/2022
Audit Date: 22, 23. 06.2022



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No.	Findings	Responsibility	Corrective action proposed	Proposed Completion date	Evidence
Layout & schematic diagram:					
1.	Air handling unit#2 serves two different classes (class E, and class D) like raw materials, primary packaging materials entrance area code: PEN001, and rooms in class D in the penicillin area	Engineering			
2.	The schematic diagram for AHU#PEN#02 did not mention the HEPA filters in symbols although there was HEPA filter in the AHU	Engineering			
3.	The room code: PEN017 in the layout was office although during site tour, we noted that there were activities done in the room like sorting and inspecting the primary packaging materials and observed there were use points for compressed air and nitrogen gas.	Engineering			
4.	The process of receiving the raw materials from the warehouse before starting the dispensing process according to SOP of dispensing process code: PN-I-011 wasn't documented	Dispensing	This process already documented in sop PN-I-011 page 3	15/11/2022	Copy of sop
5.	There wasn't a logbook for recording the operation of dispensing tools like (Scoop) and the logbook for cleaning tools code: PN-IF-010/01 not to	Dispensing	There is already two logbooks for recording cleaning tools and logbook for dispensing product with batch no	15/11/2022	Copy of logbook



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	mention the product name and batch number				
6.	The differential pressure for coating room code: PEN027 during operation of the Augram 875/125 mg tab B.N:222500 was 19 pa out of limit and the physical test was not confirmed, the operation range (12.5±2.5) pa, action limit <10pa and 15pa and not actions were taken or initiate the deviation according to SOP of monitoring of differential pressure, temperature and relative humidity code no:PN-I-058	Production - Penicillin			
7.	There wasn't differential pressure gauge after filters for nitrogen and compressed air and there wasn't a follow up for differential pressure across filters	Engineering & Production - Penicillin			
8.	- AHU#1 wasn't identified - Some pages in the logbook of follow up for AHU#1 were recorded as AHU#2 - The limit of differential pressure for bag filter >50 Pa-200 Pa, action limit <50 Pa > 195 Pa, alert limit 190 Pa, the reading from 01/05/2022 to 10/05/2022 was 195 Pa and although there was the cleaning of bag filter on 06/05/2022, the reading still high and more than alert limit so there	Engineering			



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	wasn't action taken. - The cleaning record for bag filters wasn't approved by the engineer responsible for 20/01/2022,14/02/2022,04/03/2022 ,01/04/2022,and 06/05/2022				
9.	There was no waste flow layout	Engineering			
Lyophilization					
10.	In the Lyophilizer, there was no frequency for oil vacuum pump changing and it is not clear in SOP#EN-I-144	Engineering			
Production area (sterile drops & liquid & Penicillin)					
11.	Cross contamination SOP#QA-I-064 is insufficient as it doesn't address all the risks that may take place e.g.: particulate counter changing between different areas without any addressing for it in the SOP.	QA-IPC			
12.	In the gowning area for eye drops, traces of adhesive tapes were found all over the hangers for the cloth those traces were containing particles from cloth leading to stickiness of hanger and its not being fully cleaned.	Production - Sterile drops			
13.	In SOP#PN-I-007 for cleaning of garments in the sterile area (eye drops) it stated the usage of Persil gel as detergent which isn't allowed in	Production - Sterile drops			



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	Pharma industry as it isn't odorless				
14.	At eye drops area the logbooks for temp monitoring, humidity, differential pressure and cleaning are on the same dossier also the instrument used for measurement was not coded which prevent traceability.	Production - Sterile drops			
15.	The maintenance request of the pass box wasn't created on oracle or mentioned in SOP	Production - Sterile drops			
16.	In eye drops corridor cleaning is performed by Dettol and alcohol without any frequency for changing between them also the quantity recorded of them in liters	Production - Sterile drops			
17.	In liquid preparation area class C the steps of the stairs to tank were having gaps and this lead to water stagnation in it, although the room status was clean.	Production - Liquid			
18.	In liquid preparation area some of the filters need siliconization	Production - Liquid			
19.	The SOP of visual inspection lacks the intensity in lux for the lamps	Production - Sterile drops			
20.	Lack of line clearance the labelling machine for the eye drops there was a label (of different product	Production - Sterile			



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	phramapress) in -between the machine	drops			
21.	There was no SOP to handling the privilege of equipment	Production - Sterile drops			
22.	There was no thermal mapping for staging area	QA- Validation			
23.	During the process of blistering for Augram 1g B.No:(222482) in blistering machine (Hoonga) the time during the audit is 03:00 pm and on the panel of the machine is 05:34pm	Production - penicillin			
24.	There was photocopy of the batch record of Augram 875/125mg, B.No (222482) in the production area	Production - penicillin			
25.	In the penicillin area, there was no risk assessment to prevent mix-up as the bottles transfer to another area not labelled	Production - penicillin			
QC laboratories :					
26.	In the QC lab, there was a finished product (Colona) and (Flu-C) although they were not under analysis as its manufacture date was 5/2022.also a roll of printed aluminum foil was found and have no status	QC			
27.	The QC receiving & analysis logbook were not coded and its data were not relevant to SOP So, it isn't controlled by document control	QC			



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